

DEC 21 2004

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510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Lonnie Witham

Proprietary Name: Medallion Modular Hip System

Common Name: Total hip femoral component

Classification Name: Prosthesis, hip, semi-constrained, metal/polymer, porous, uncemented (888.3558)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Modular Hip Stem (Apex Surgical, LLC; K000788)
- PRO-FEMUR Hip System (Wright Medical Technology, Inc; K012091, K003016)
- Reach Femoral Component (Biomet, Inc; K000760)

Device Description:

The Medallion Modular Hip System is a complete system of femoral stem implants. The implants have a proximal female dovetail groove attachment site that is utilized for attaching various modular trunnions. The modular trunnions have a distal male semi-dovetail projection that engages the female dovetail groove on one side in such a way that a keyway is defined between the two components. The implants also include a key that is to be wedged in the keyway to lock the three components together and prevent relative sliding.

Intended Use:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Correction of functional deformity
- 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- 5) Revision of previously failed total hip arthroplasty.

Summary of Technologies: The Medallion Modular Hip System has the same indications for use, intended use, and materials as the predicate devices. Testing demonstrates that the design has sufficient strength for the intended use.

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Non-Clinical Testing:

The information presented demonstrates that the Medallion Modular Hip System is substantially equivalent to currently marketed predicate devices. The differences between the Medallion Modular Hip System and the predicates are not significant and have shown not to present additional safety or efficacy issues.

Clinical Testing: No clinical testing was conducted for this design.

All trademarks are property of Biomet, Inc.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Mr. Lonnie Witham
Senior Regulatory Specialist
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K041850

Trade Name: Medallion Modular Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated
uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: July 7, 2004
Received: July 8, 2004

Dear Mr. Witham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia Witten', is positioned above the printed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

16041850

Indications for Use

510(k) Number (if known):

Device Name: Medallion Modular Hip System

Indications For Use:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Correction of functional deformity
- 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- 5) Revision of previously failed total hip arthroplasty.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)
**Division of General, Restorative
and Neurological Devices**

510(k) Number 16041850